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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,861	11/01/2001	Johan Ericson	21882-502	6942

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,861	ERICSON, JOHAN	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *see attached Notice to Comply*.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a method of guiding the fate of differentiation of a cell into a specific cell type by contacting the cell with a Groucho-interacting protein (GIP), classified in class 435, subclass 375.

II. Claims 1-24, drawn to a method of guiding the fate of differentiation of a cell into a specific cell type by contacting the cell with a Groucho-interacting protein (GIP), classified in class 424, subclass 9.1.

III. Claims 25-28, 42-44 and 57, drawn to an isolated polypeptide of SEQ ID NO:7 and 13, classified in class 530, subclass 350.

IV. Claims 29-38, drawn to an isolated DNA encoding the amino acid sequences of SEQ ID NO:7 and 13, classified in class 536, subclass 23.1.

V. Claims 39-41, drawn to an antibody that binds to the amino acid sequences of SEQ ID NO:7 and 13, classified in class 530, subclass 387.1.

VI. Claim 61, drawn to an antibody that binds to the GIP/Groucho-corepressor protein complex, classified in class 530, subclass 387.1.

VII. Claims 45-54, drawn to a purified GIP/Groucho-corepressor protein complex, classified in class 530, subclass 350.

VIII. Claims 55-60, drawn to a chimeric polypeptide comprising a portion of GIP and a portion of Groucho-corepressor, classified in class 435, subclass 69.1.

IX. Claims 62-63, 69-70, drawn to a kit comprising antibodies specific to GIP, Groucho-corepressor and GIP/Groucho-corepressor-complex and method of diagnosing the proteins or complex classified in class 435, subclass 7.1.

X. Claims 64-68, 71 drawn to a method of identifying agents that modulates, disrupt, or interact with the GIP/Groucho-corepressor-complex, and

treating a disease involving altered levels of GIP/Groucho-corepressor-complex classified in class 435, subclass 4 and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case method of guiding the fate of differentiation of a cell by contacting the cell with GIP in-vitro is distinct from method of guiding the fate of differentiation of a cell by contacting the cell with GIP in-vivo. In-vitro method may involves the differentiation of previously established neuronal cells lines, where as differentiation of cells in vivo may involves differentiation of terminally matured neuronal cells. Furthermore, in-vivo method requires sites specific delivery of the GIP polypeptide and evaluation of cell differentiation via methods that are not required for an in-vitro method. Thus these invention are distinct, since use or one is not required for another.

Inventions III (GIP protein), IV (GIP DNA), V (GIP ab), VI (ab to complex) VII (GIP/Groucho-corepressor-complex) and VIII (GIP/Groucho-corepressor fusion protein) are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case proteins, nucleic acid molecules, proteins, and antibodies are structurally and functionally distinct product. For example, proteins and antibodies are biologically active compounds wherein the nucleic acids require an expression vector to express the encoded product. In addition proteins could also be isolated from natural sources besides making them by recombinant means (see (MPEP § 806.05(f)). Thus these inventions are distinct and are of separate uses.

Inventions IX and X are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

instant case a kit and its use to detect GIP/Groucho-corepressor-complex requires materially different reagents and protocols as compare to method of identifying agents that modulates GIP/Groucho-corepressor-complex stability or activity. In addition the agents that modulates the stability or activity of GIP/Groucho-corepressor-complex are not required for the diagnosis of GIP or Groucho-corepressor polypeptides or GIP/Groucho-corepressor-complex. Thus these inventions are distinct and are of separate uses.

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case besides guiding the fate of neuronal differentiation the GIP polypeptide could also be used to generate GIP specific antibodies. Thus these inventions are distinct and are of separate uses.

Inventions of groups I-II are distinct from inventions of groups IV-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case use of invention IV (GIP DNA), V (GIP ab), VI (ab to complex) VII (GIP/Groucho-corepressor-complex) or VIII (GIP/Groucho-corepressor fusion protein) are not required for the inventions of group I and II. Invention of group I and II only requires the use of GIP protein to stimulate cells. Thus these inventions are distinct and are of separate uses.

Inventions IX is distinct from inventions of groups V and VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case besides making a diagnostic kit the antibodies of invention V and VI could also be used to affinity columns for protein purification. Thus these inventions are distinct and are of separate uses.

Inventions X is distinct from inventions of group VII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case besides screening the compounds that modulates GIP/Groucho-corepressor-complex activity the complex could also be used to raise antibodies against the GIP/Groucho-corepressor-complex. Thus these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sumesh Kaushal
Examiner Art Unit 1636

JEFFREY FREDMAN
PRIMARY EXAMINER

Notice To Comply

With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application (see MPEP 2422.03).

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

> **The instant specification fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures because**: *The specification fail to provide SEQ ID NO(s) for the nucleotide sequences disclosed in claim 24, 42 and pages 5, 6,*

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the SIX MONTHS statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office. Please direct all replies to the United States Patent and Trademark Office via one of the following:

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